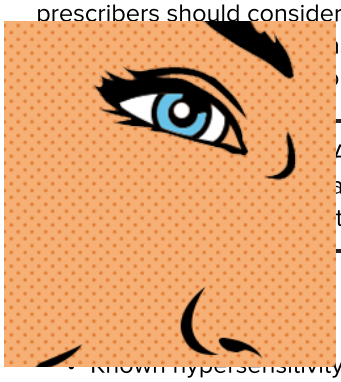
Fanapt®
(iloperidone) tablets
1 mg, 2 mg, 4 mg, 6 mg, 8 mg, 10 mg, 12 mg


## INDICATION AND IMPORTANT SAFETY INFORMATION

Fanapt® (iloperidone) is indicated for the treatment of schizophrenia in adults. In choosing among treatments, prescribers should consider the ability of Fanapt® to prolong the QT interval and the use of other drugs first. ...sider the need to titrate Fanapt® slowly to avoid orthostatic hypotension, which may lead ...mpared to some other drugs that do not require similar titration.



**...ASED MORTALITY IN ELDERLY PATIENTS WITH DEMENTIA-RELATED PSYCHOSIS: Elderly ...ated psychosis treated with antipsychotic drugs are at an increased risk of death. Fanapt® is ...tients with dementia-related psychosis.**

- Known hypersensitivity to Fanapt® or to any components in the formulation. Anaphylaxis, angioedema, and other hypersensitivity reactions have been reported.


**TIONS**

ed for treatment of patients with dementia-related psychosis. There was a higher incidence of cerebrovascular adverse events, including death, compared to placebo-treated patients.

- QT prolongation: Fanapt® prolongs QT interval and may be associated with arrhythmia and sudden death—consider using other antipsychotics first. Avoid use of Fanapt® in combination with other drugs that are known to prolong QTc; use caution and consider dose modification when prescribing Fanapt® with other drugs that inhibit Fanapt® metabolism. Monitor serum potassium and magnesium in patients at risk for electrolyte disturbances.
- Neuroleptic malignant syndrome, a potentially fatal symptom, has been reported in association with antipsychotic drugs including Fanapt®. Manage with immediate discontinuation of drug, treatment if needed, and close monitoring.
- Tardive dyskinesia: The risk of tardive dyskinesia may increase as the duration of treatment and total cumulative dose increases. Discontinue Fanapt® if clinically appropriate.
- Metabolic changes: Atypical antipsychotic drugs have been associated with metabolic changes that may increase cardiovascular/cerebrovascular risk. These metabolic changes include hyperglycemia, dyslipidemia, and weight gain. Monitor patients for symptoms of hyperglycemia including polydipsia, polyuria, polyphagia, and weakness. Monitor glucose regularly in patients at risk for diabetes. Undesirable alterations in lipids have been observed in patients treated with atypical antipsychotics. Weight gain has been reported; monitor weight.
- Seizures: Use Fanapt® cautiously in patients with a history of seizures or with conditions that lower seizure threshold.
- Orthostatic hypotension: Dizziness, tachycardia, and syncope can occur with standing. More rapid titration would be expected to increase the rate of orthostatic hypotension and syncope.
- Fanapt® may cause somnolence, postural hypotension, motor and sensory instability, which may lead to falls causing fractures or other injuries. For patients with diseases, conditions, or medications that could exacerbate these effects, complete fall risk assessments initially and recurrently during therapy.
- Leukopenia, neutropenia, and agranulocytosis have been reported with antipsychotics. Patients with a pre-existing low white blood cell count (WBC) or a history of leukopenia/neutropenia should have their complete blood count (CBC) monitored frequently during the first few months of therapy and should discontinue Fanapt® at the first sign of a decline in WBC in the absence of other causative factors.
- Hyperprolactinemia: As with other drugs that antagonize dopamine D2 receptors, Fanapt® elevates prolactin levels. Galactorrhea, amenorrhea, gynecomastia, and impotence have been reported with prolactin-elevating compounds.
- Body temperature regulation: Appropriate care is advised when prescribing Fanapt® for patients who will be experiencing conditions which may contribute to an elevation in core body temperature.
- Dysphagia: Esophageal dysmotility and aspiration have been associated with antipsychotic drug use. Fanapt® should be used cautiously in patients at risk for aspiration pneumonia, including the elderly and those with advanced Alzheimer's dementia.
- Suicide: Closely supervise high-risk patients.
- Priapism: Cases have been reported in association with Fanapt® treatment.
- Potential for cognitive and motor impairment: Use caution when operating machinery.

**ADVERSE REACTIONS**

- Commonly observed adverse reactions (incidence ≥5% and 2-fold greater than placebo) were: dizziness, dry mouth, fatigue, nasal congestion, orthostatic hypotension, somnolence, tachycardia, and weight increased.

**DRUG INTERACTIONS**

- The dose of Fanapt® should be reduced by one-half in patients co-administered a strong CYP2D6 or CYP3A4 inhibitor.

**USE IN SPECIFIC POPULATIONS**

- Fanapt® may cause extrapyramidal symptoms and/or withdrawal symptoms in neonates with third trimester exposure. Nursing mothers are advised not to breastfeed while taking Fanapt®.
- The safety and effectiveness of Fanapt® has not been established in children and adolescents.
- Fanapt® is not recommended for patients with severe hepatic impairment.
- The dose of Fanapt® should be reduced by one-half in patients who are poor metabolizers of CYP2D6.

Please see full Prescribing Information, including BOXED WARNING.

**Full Prescribing Information**

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